



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1960]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch:

The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on revisions to Forms FDA 3500, 3500A, and 3500B used in the FDA Medical Products Reporting Program.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MedWatch: The FDA Medical Products Reporting Program--(OMB Control Number 0910-0291)--Extension

I. Background

To ensure the marketing of safe and effective products, postmarketing adverse outcomes and product problems must be reported for all FDA-regulated human healthcare products, including drugs (prescription, nonprescription, and compounded), biologics, medical devices, dietary supplements and other special nutritional products (e.g. infant formula and medical foods), and cosmetics. In addition, FDA has regulatory responsibility for some tobacco products and an interest in receiving reports about adverse outcomes and product problems for these products.

Under sections 505, 512, 513, 515, 519, and 903 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), (21 U.S.C. 355, 360b, 360c, 360e, 360i, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the FD&C Act (21 U.S.C. 352(f)(2)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the FD&C Act, it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling. Under section 502(t)(2) of the FD&C Act, devices are considered to be misbranded if there has been a failure or refusal to give required notification or to furnish required material or information required under section 519 of the FD&C Act. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 of the FD&C Act (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 503B, 760, and 761 of the

FD&C Act. Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

FDA regulates the safety (i.e., adulteration) of dietary supplements under section 402 of the FD&C Act (21 U.S.C. 342). Dietary supplements do not require premarket approval by FDA, and the Agency bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Under section 761(b)(1) of the FD&C Act (21 U.S.C 379aa-1(b)(1)), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States.

Since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, their patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use. When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these provisions for reporting on human medical products (except vaccines) during their postapproval and marketed lifetimes, three forms (collectively known as the MedWatch forms) are available from the Agency. Form FDA 3500 may be used for voluntary (i.e., not mandated by law or regulation) reporting by healthcare professionals. Form

FDA 3500B is written in plain language and may be used for voluntary reporting (i.e., not mandated by law or regulation) by consumers (i.e., patients and their caregivers). Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation).

Respondents to this collection of information are healthcare professionals; medical care organizations and other user facilities (e.g. extended care facilities, ambulatory surgical centers); consumers; manufacturers of biological, dietary supplement and drug products, or medical devices; and importers.

## II. Use of Form FDA 3500 (Voluntary Reporting)

This voluntary version of the form may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1). Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System (see <http://vaers.hhs.gov>), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation, section 761(b)(1) of the FD&C Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event

report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals, and especially by consumers, of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were previously received by the Agency on paper versions of Form FDA 3500 (by mail or fax). Currently, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal (<http://www.safetyreporting.hhs.gov/>). In that case, Form FDA 3500 is not used.

Form FDA 3500 may be used to report to the Agency serious adverse events, product problems, and product use errors and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) or electronically submit a report via the MedWatch Online Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/>). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription (over the counter (OTC)) human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (<http://www.safetyreporting.hhs.gov/>).

### III. Use of Form 3500B (Consumer Voluntary Reporting)

This voluntary version of the form may be used by consumers (i.e. patients and their caregivers) to submit reports not mandated by Federal law or regulation. Individual patients or their caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer.

FDA supports and encourages direct reporting to the Agency by consumers of suspected serious adverse outcomes and other product problems associated with human medical products, (<http://www.fda.gov/Safety/ReportaProblem/default.htm>). Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler (Ref. 1), the program has been promoting and facilitating voluntary reporting by both the general public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Public Law 107-109).

On March 25, 2008, section 906 of the Food and Drug Administration Amendments Act (Public Law 110-85) amended section 502(n) of the FD&C Act and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/safety/medwatch](http://www.fda.gov/safety/medwatch), or call 1-800-FDA-1088."

Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report "side effects" to FDA and provide contact information to permit reporting via the MedWatch process.

Since 2013, FDA has made available Form FDA 3500B. It was proposed during the previous authorization in 2012 and is a version of Form FDA 3500 that is tailored for consumers and written in plain language (in conformance with the Plain Writing Act of 2010 (Public Law 111-274) <http://www.gpo.gov/fdsys/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf>). Form FDA 3500B evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies, and with extensive input from consumer advocacy groups and the general public.

Form FDA 3500B may be used to report to the Agency adverse events, product problems, and product use errors. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf>) or electronically submit a report via the MedWatch Online Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/>). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription OTC human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (<http://www.safetyreporting.hhs.gov/>).

#### IV. Use of Form FDA 3500A (Mandatory Reporting)

##### A. Drug and Biological Products

In sections 503B, 505(j), and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human prescription drug products be



made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to the FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biologics). Mandatory reporting of adverse reactions for HCT/Ps has been codified in 21 CFR 1271.350. Postmarketing Safety Reports--Changes in Format Starting in 2015

Current requirements specify that postmarket adverse experience reports must be submitted on paper on FDA Form 3500A (or the CIOMS (Council for International Organizations of Medical Sciences) I form) for serious, unexpected adverse experiences from a foreign source), but for the last several years the Agency has accepted electronic submissions in lieu of the paper Form FDA 3500A on the condition they are submitted in a manner that the Agency can process, review, and archive. On June 10, 2014, the Agency issued a final rule entitled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements" (79 FR 33072) that requires electronic submission of all mandatory postmarket safety reports, including individual case safety reports. Entities with mandatory reporting obligations must implement this rule within 1 year of the issuance date (by June 9, 2015). For more information see: <http://www.gpo.gov/fdsys/pkg/FR-2014-06-10/pdf/2014-13480.pdf>.

#### B. Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information, as the Secretary of Health and Human Services may, by regulation, reasonably be required to provide assurance that such devices are not adulterated or misbranded and to

otherwise assure its safety and effectiveness. The Safe Medical Devices Act of 1990 (Public Law 101-629), signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803 (part 803). Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), signed into law October 26, 2002, amended section 519 of the FD&C Act. The MDUFMA amendment (section 303) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.

### C. Nonprescription Drug Products and Dietary Supplements

Section 502(x) in the FD&C Act (21 U.S.C. 352(x)) implements the requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462), which became law on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription OTC human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements. Electronic reports for dietary supplements may be submitted using the Safety Reporting Portal (<http://www.safetyreporting.hhs.gov/>). Paper-based dietary supplement reports may be submitted using Form FDA 3500A.

## V. Proposed Modifications to Existing Forms 3500, 3500A, and 3500B

### A. General Changes

The proposed modifications to Forms FDA 3500 and 3500A reflect changes that will bring the forms into conformation, since the previous authorization in 2012, with current regulations, rules, and guidances.

### B. Changes Proposed for Form FDA 3500

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD-MMM-YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the optical character recognition (OCR) software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C (Returned to Manufacturer On), D7, E4 (Expiration Date), E6, and E7.

In recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data

(<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCA/FDASIA/UCM410474.pdf>) developed in response to the requirement in section 907 of the Food and Drug Administration Safety and

Innovation Act (FDASIA) of 2012 (Public Law 112-144), changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests "Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)." Instead, it is proposed that a new race and ethnicity field be added to section A, "Patient Information." The proposed ethnicity field will be numbered 5a and state "Ethnicity (Check single best answer)" with corresponding checkboxes for "Hispanic/Latino" and "Not Hispanic/Latino." Adjacent to this field, the "Race" field will be numbered 5b and state "Race (Check all that apply)." It will contain checkboxes for "Asian," "American Indian or Alaskan Native," "Black or African American," "White," and "Native Hawaiian or Other Pacific Islander."

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place, and increase the likelihood that this information is entered. First, it is proposed that sections C, "Product Availability," and D, "Suspect Product(s)," on the current form be merged into a single section to be entitled section C, "Suspect Products." In the new section C, field C1 will be used to request data for "Name and Strength," "Manufacturer/Compounder," "Lot #," and "NDC # or Unique ID #" for up to two suspect medical products. Fields for "Lot #" and "NDC # or Unique ID #" on the current form (D6 and D9) will be removed on the proposed form. The single field for "Product Availability" (section C on the current form) will be relocated to C2 on the proposed form, immediately following the field for product name, strength, manufacturer/compounder, Lot #, and NDC/Unique ID #. As a result of sections C and D being merged, the remaining sections on the form will be resequenced

accordingly (i.e. section E currently labeled "Suspect Medical Device" will become section D with the same label, section F will become section E, and section G will become section F).

In 2013, the Drug Quality and Security Act (Public Law 113-54) added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. In addition to mandatory reporting, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of the MedWatch forms (i.e. Forms FDA 3500 and 3500B) to improve the ability to rapidly identify reports involving compounded drugs. The existing field (section D, field D1) that contains the descriptor "Manufacturer" will be relabeled "Manufacturer/Compounder." Correspondingly, a checkbox for "Compounder" will be added to the existing field (section G, field G4) "Also Reported to." It is proposed that a new field be added to the section entitled "Suspect Products." The new field will be numbered and include a descriptor "Is Product Compounded or Over-the-Counter? (Check all that apply)" with corresponding checkboxes for "Compounded" and "Over-The-Counter" (for up to two suspect products). The instructions to the form will be updated accordingly. The form remains a three-page form with all the main data fields on page one, with instructions for use and a self-addressed, postage-paid return mailer on the reverse side of page one, and page three being a continuation page for additional information should reporters need extra space.

### C. Changes proposed for Form FDA 3500A

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD-MMM-YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the OCR software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C7, D4 (Expiration Date), D6, D7, D10 (Returned to Manufacturer on), F6, F8, F11, F13, G4, and H4.

In recognition of OMB's 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data

(<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/UCM410474.pdf>) developed in response to the requirement in section 907 of FDASIA, changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests "Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)." Instead, it is proposed that a new race and ethnicity field be added to section A, "Patient Information." The proposed ethnicity field will be numbered 5a,

and state "Ethnicity (Check single best answer)" with corresponding checkboxes for "Hispanic/Latino" and "Not Hispanic/Latino." Adjacent to this field, the "Race" field will be numbered 5b, and state "Race (Check all that apply)." It will contain checkboxes for "Asian," "American Indian or Alaskan Native," "Black or African American," "White," and "Native Hawaiian or Other Pacific Islander."

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place and increase the likelihood that this information is entered. For consistency and clarity, it is proposed that many of the fields in the suspect products sections on Forms FDA 3500 and 3500A be mirrored. For Form FDA 3500A, it is proposed that the current section C, field C1, "Name (Give labeled strength & mfr/labeler)," also be used to request data for "Lot #" and "NDC # or Unique ID #." Section C, field C1 will be relabeled "Name, Manufacturer/Compounder, Strength." Proposed field C1 will contain distinct areas for "Name and Strength," "Manufacturer/Compounder," "NDC # or Unique ID #," and "Lot #" for up to two suspect products. Since the information will now be captured in proposed field C1, separate fields for "Lot #" and "NDC #/Unique ID #" (C6 and C9 from the current form) will be removed. It is also proposed that a new field be added, numbered C2, and containing the descriptor "Product Available for Evaluation?" with checkboxes for "Yes," "No," and "Returned to Manufacturer on (DD-MMM-YYYY)." Consequently, the currently numbered field C2, "Dose, Frequency & Route Used," will be renumbered C3. It will also be reformatted to have three distinct areas for dose, frequency, and route, respectively, for up to two suspect products. Current field C3, "Therapy Dates," will be renumbered C4, and current field C4, "Diagnosis for Use," will be renumbered C5. Current field C5, "Event Abated After Use Stopped or Dose

Reduced," will be renumbered C8, and field C8, "Event Reappeared After Reintroduction?" will be renumbered C9. Field C7 remains a field for expiration date, and field C10 will remain a field for concomitant medical products and therapy dates.

In 2013, the Drug Quality and Security Act added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. To facilitate implementation of this mandatory reporting requirement, changes will need to be made to the existing Form FDA 3500A. It is proposed that a new field be added to section G1 that contains the descriptor "Compounding Outsourcing Facility 503B?" with a corresponding checkbox for "Yes." It is also proposed that a new field be added to section C, "Suspect Products." The new field will be numbered C6 and include a descriptor "Is Product Compounded or Over-the-Counter (Check all that apply)?" with corresponding checkboxes for "Compounded" and "Over-The-Counter" (for up to two suspect products). The instructions to the form will be updated accordingly.

Additionally, for clarity, in section G, field G5, the area labeled "(A)NDA #" will be split into two separate areas--one for "ANDA #" and one for "NDA #."

#### D. Changes proposed for Form FDA 3500B

For consistency, and to improve the quality of the data received, the changes being proposed on the voluntary Form FDA 3500 (for use by healthcare professionals) are also being proposed on the voluntary Form FDA 3500B (for use by consumers). Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information. In section D, the field entitled "Age (at time the problem occurred) or Birth Date" will be



separated into separate fields for age and date of birth. In the field for "Age", checkboxes for years, months, weeks, and days will be added to permit clarity about the age of the patient. Similarly, for the field in section D labeled "Weight," checkboxes for pounds (lb) and kilograms (kg) will be added to permit clarity about the patient's weight. The instructions will be modified accordingly. To permit clarity about the dates being reported, field labels and instructions will be modified to ask the reporter to use the format DD-MMM-YYYY. A watermark will be added to the field to prompt the reporter to respond using this format. This will also reduce the data entry burden by making the form more easily scanned by the OCR software used by FDA. All of the date fields on the form will be affected by this proposed change. These include section A (date the problem occurred, death), section B (expiration date, date the person first started taking or using this product, date the person stopped taking or using this product), section C (date the implant was put in, date the implant was taken out), section D (date of birth), and section E (today's date).

A formatting modification to the field in section D that is currently labeled "Race" is being proposed in recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (<http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/UCM410474.pdf>) developed in response to the requirement in section 907 of FDASIA (Public Law 112-144). It is proposed that the field be relabeled "Race (Check all that apply)" and contain checkboxes for "Asian," "American Indian or Alaskan Native," "Black or African American," "White," and "Native Hawaiian or Other Pacific Islander." It is also proposed that the field contain an adjacent area

labeled "Ethnicity (Check single best answer)" with corresponding checkboxes for "Hispanic/Latino" and "Not Hispanic/Latino."

As discussed previously in this notice, section 503B of the FD&C Act requires outsourcing facilities to report adverse events to FDA. In addition to mandatory reporting, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of Forms FDA 3500 and 3500B to improve the ability to rapidly identify reports involving compounded drugs. FDA proposes to add a field to section B with the label "Is product Compounded or Over-The-Counter (Check all that apply)" and corresponding checkboxes for "Compounded" and "Over-The-Counter."

Finally, to improve clarity and to be consistent with Form FDA 3500, FDA proposes to reword the last field of section E that currently asks "May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?" to "If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box."

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

FDA Center/21 CFR Section/ FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total
Center for Biologics Evaluation and Research/ Center for Drug Evaluation and Research: Form 3500.....	14,727	1	14,727	0.66 (40 minutes)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, 1271.350).....	599	98	58,702	1.21	71,029

Center for Devices and Radiological Health: Form 3500.....	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (§ 803).....	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition: Form 3500.....	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A.....	1,659	1	1,659	1.21	2,007
Center for Tobacco Products Form 3500.....	39	1	39	0.66 (40 minutes)	26
All Centers Form 3500B.....	13,750	1	13,750	0.46 (30 minutes)	6,325
Total					909,274

## VI. References

1. Kessler, D. A, "Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems," Journal of the American Medical Association, 269(21), June 2, 1993, pp. 2765-2768.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.